UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,198	03/26/2004	Didier Communi	9409/2113B	2940

29933 7590 01/04/2007

PALMER & DODGE, LLP
KATHLEEN M. WILLIAMS
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER	
LI, RUIXIANG	
ART UNIT	**PAPER NUMBER**
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,198	COMMUNI ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *8-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on 10/12/2006 has been entered in full. Claims 4 and 6 have been amended. Claims 20-22 have been added. Claims 1-23 are pending. Claims 1-7 and 20-23 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejection of claims 4-7 under 35 U.S.C. 112, first paragraph for written description has been withdrawn in view of amended claims.

Claim Rejections Under 35 U.S.C.§ 101 and §112, 1st Paragraph

The rejections of claims 1-7 under 35 U.S.C. § 101 and 35 U.S.C. §112, 1st paragraph are maintained for the reasons set forth in the previous office action. New claims 20-23 are also rejected on the same basis.

Applicants cite a number of references and argue that UTP is known in the art as a therapeutic for Cystic Fibrosis.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the instant invention is drawn to an isolated antibody that binds to a protein receptor comprising SEQ ID NO: 2 and a composition comprising the antibody. The art recognized utility for UTP does not renders the instant claimed invention a specific and substantial utility because there is no structural or functional link between UTP and antibody that binds to the protein comprising SEQ ID NO: 2.

Moreover, as taught in the art, UTP activates a number of receptors, not only one. For instance, Nicholas et al. teach that UTP activates both P2Y2 and P2Y4 *(Molecular Pharmacology* 50:224-229, 1996; see, e.g., Abstract*)*. There is no evidence on the record showing that UTP is the natural ligand of the receptor of SEQ ID NO: 2 and exerts such a therapeutic effect via the protein receptor comprising SEQ ID NO: 2.

Applicants cite a number of references and argue that there is a reasonable correlation between the activity in question (UTP mediated signaling of P2Y4 (SEQ ID NO: 2) and the asserted utility (treating cystic fibrosis). That is, the actions of extracellular nucleotides (UTP) are mediated by P2Y4 receptors as disclosed in the specification, and that P2Y4 receptors are a therapeutic target for the treatment for cystic fibrosis, as asserted in the specification.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, the effective filing date of the instant application is

considered to be 11/12 1998, i.e., the filing date of 09/077173, whereas the claimed earliest foreign priority date is 11/21/1995. Thus, all cited references are after the effective filing date of the instant application, not prior to the effective filing date of the instant application (top of page 9 of Applicant's response). Otherwise, the instant claims would be rejected based upon a prior art rejection using the art cited by Applicants in the present response.

Secondly, the instant specification asserts that the polypeptide of SEQ ID NO: 2 is a pyrimidinergic receptor, preferably a UTP-specific receptor (lines 25-27 of page 2) and an agonist or antagonist may be used in a pharmaceutical composition in the treatment of cystic fibrosis (lines 10-11 of page 7). These asserted utilities are not specific and substantial because they do not identify or reasonably confirm a "real world" context of use. The assertion that an agonist or antagonist may be used in a pharmaceutical composition in the treatment of cystic fibrosis (lines 10-11 of page 7) is a clear invitation for further research because either an agonist or antagonist, not both, may be used for treatment of cystic fibrosis. More importantly, the disclosure neither identifies the biological functions of the polypeptide of SEQ ID NO: 2 nor establishes a causative link between the polypeptide of SEQ ID NO: 2 and cystic fibrosis. Clearly, further research would be required to identify the physiological roles of the molecules of the present invention, to establish a causative link between the polypeptide of SEQ ID NO: 2 and cystic fibrosis.

Thirdly, the sequence and prior art search does not reveal that the polypeptide of SEQ ID NO: 2 of the present invention or the antibody that binds to the polypeptide has a well-established utility. The specific physiological roles of the polypeptide of SEQ ID NO: 2 remain elusive even after the filing date of the instant application. As taught by Nicholas et al. *(Molecular Pharmacology* 50:224-229, 1996*)*, "unambiguous evidence for regulated release of uridine nucleotides is needed to confirm the physiological importance of pyrimidinergic receptor-signaling responses (the third paragraph of right column of page 228). Even the specific cellular activities of uridine nucleotides, the ligand of the receptor protein of SEQ ID NO: 2 of the present invention, remain unproved (top of left column of page 229).

The cited references by Applicants report various studies related to P2Y4 receptor and UTP; they do not establish a causative link between the polypeptide of SEQ ID NO: 2 and cystic fibrosis. The cited references by Applicants clearly document that even after the effective filing date of the instant application, the functional activities of the P2Y4 receptor is unclear and researchers in the field still investigate the physiological roles of the polypeptide of SEQ ID NO: 2. Thus, the claimed invention is not useful in its current form under 35 U.S.C. 101.

Claim Rejections under 35 USC § 112, 1st paragraph (Written description)

The rejection of claims 2 and 3 under 35 U.S.C. 112, first paragraph, is maintained for the reasons set forth in the previous office action. New claims 20-23 are also rejected on the same basis.

Citing case law, Applicants argue that the structure and functional properties of the claimed antibodies are disclosed in the instant specification, they meet the written description requirement.

Applicants' argument has been fully considered, but is not deemed to be persuasive because while providing adequate description for an antibody that binds to the polypeptide comprising SEQ ID NO: 2, the instant disclosure fails to provide adequate description for an antibody that is an agonist or antagonist of the polypeptide comprising SEQ ID NO: 2. The specification does not disclose the structural features of an antibody that acts an agonist or antagonist. The specification does not even disclose a single antibody that is an agonist or antagonist of the polypeptide comprising SEQ ID NO: 2.

Citing Example 16 of the Written Description Guidelines issued by the USPTO, Applicants argue that because the instant disclosure meets the criteria with respect to the antigen P2Y4, the disclosure meets the requirement under 35 U.S.C. 112, first paragraph, as providing an adequate written description of the claimed invention.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Example 16 is related to an antibody, not an antibody that acts as an agonist or antagonist. Moreover, as acknowledged in the specification (line 11 of page 18), no specific antagonist was available for any P2Y subtype at the time of the filing of the instant application, further indicating that producing an antibody that acts as an agonist or antagonist of the antigen that the antibody binds is not conventional in the art. Thus, Applicants were not in possession of the invention of claims 2, 3, and 20-23.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
December 28, 2006